



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: March 17, 2020

Subject: Efficacy Review for ECAFLO ANOLYTE,
EPA Reg. No. 91582-1 (DP Barcode: 456904, E-Submission: 47903)

From: Kristen Willis, Chief
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Applicant: Danolyte Global, Inc.
9216 Bond Street, Overland Park, KS 66214

Formulation from the Label:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Hypochlorous Acid0.046%
<u>Other Ingredients</u>	99.954%
Total.....	100.0%

I BACKGROUND

Product Description (as packaged, as applied): RTU Liquid

Submission type: Fast-track amendment- 320

Currently registered efficacy claim(s): hospital and healthcare disinfectant (bactericidal, virucidal, tuberculocidal), non-food contact sanitizer for use on hard, non-porous surfaces and soft surfaces.

Requested action(s): Add Emerging Viral Pathogen claim

Documents considered in this review:

- Cover Letter/Terms of Registration Letter from applicant to EPA dated March 17, 2020
 - Note: One of the 3 supporting viruses was only identified in the cover letter and is not on the proposed label.
- Data Matrix (EPA Form 8570-35) dated March 10, 2020
- Efficacy studies (MRID 49680701, 49680706, 49197002, 49680703)
- Proposed label undated
- Efficacy review for Reg. No. 82341-1 DP 428914

II STUDY CONCLUSIONS

MRID	Emerging virus claim	Organism(s)	Type of Virus (family)	Surface Type	Application Method(s) and/or Dilution	Contact Time	Soil load	Data support label claims?
49680701	Enveloped Viruses	Adenovirus Type 1	Large, non-enveloped	Hard non-porous surface	RTU liquid	10 minutes	5% serum	Yes
49680706	Enveloped Viruses, Large and small non-enveloped virus	Rhinovirus Type 16	Small, non-enveloped	Hard non-porous surface	RTU liquid	10 minutes	5% serum	Yes
49197002	Enveloped Viruses, Large and small non-enveloped virus	Canine parvovirus	Small, non-enveloped	Hard non-porous surface	RTU liquid	10 minutes	5% serum	No. This organism is not on the product label.
49680703	Enveloped Viruses, Large and small non-enveloped virus	Norovirus	Small, non-enveloped	Hard non-porous surface	RTU liquid	10 minutes	5% serum	Yes ¹

¹ This virus was not included on the cover letter or the proposed label however it is eligible to support a claim if the registrant chooses.

IV LABEL COMMENTS

Label Date: Undated

1. The proposed label claims that the product, **ECAFLO ANOLYTE, (EPA Reg. No. 91582-1)**, qualifies for an emerging viral pathogens claim.

For an emerging viral pathogen that is a/an...	...following the directions for use for the following organisms on the label:
Enveloped virus	
Large non-enveloped virus	Adenovirus Type 1
Small non-enveloped virus	Rhinovirus Type 16

These claims are partially **acceptable** as they are supported by the cited data however the supporting viruses are not accurately listed in the table or on the terms of registration. Based on these two viruses only claims for enveloped and large non-enveloped emerging viruses are supported. The proposed label language should exactly match the following:

“This product qualifies for emerging viral pathogen claims per the EPA’s ‘Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels’ when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:

-Enveloped Viruses

-Large Non-Enveloped Viruses

For an emerging viral pathogen that is a/an...	...following the directions for use for the following organisms on the label:
Enveloped virus	Adenovirus Type 1 Rhinovirus Type 16
Large non-enveloped virus	Rhinovirus Type 16

Acceptable claim language:

[Product name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, [porous and/or non-porous surfaces]. Therefore, [product name] can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on [hard, porous/non-porous surfaces]. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by ***[name of emerging virus]***. ***[Product name]*** kills similar viruses and therefore can be used against ***[name of emerging virus]*** when used in accordance with the directions for use against ***[name of supporting virus(es)]*** on ***[hard, porous/non-porous surfaces]***. Refer to the ***[CDC or OIE]*** website at ***[website address]*** for additional information.”

2. If the registrant chooses, they can revise the terms of registration to include Adenovirus Type 1, Rhinovirus Type 16, and norovirus and revise the label to exactly match the following.

“This product qualifies for emerging viral pathogen claims per the EPA’s ‘Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels’ when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:

-Enveloped Viruses

-Large Non-Enveloped Viruses

- Small Non-Enveloped Viruses

For an emerging viral pathogen that is a/an...	...following the directions for use for the following organisms on the label:
Enveloped virus	Adenovirus Type 1 Rhinovirus Type 16 Norovirus
Large non-enveloped virus	Rhinovirus Type 16 Norovirus
	Rhinovirus Type 16 Norovirus

Acceptable claim language:

[Product name] has demonstrated effectiveness against viruses similar to ***[name of emerging virus]*** on hard, ***[porous and/or non-porous surfaces]***. Therefore, ***[product name]*** can be used against ***[name of emerging virus]*** when used in accordance with the directions for use against ***[name of supporting virus(es)]*** on ***[hard, porous/non-porous surfaces]***. Refer to the ***[CDC or OIE]*** website at ***[pathogen-specific website address]*** for additional information.

[Name of illness/outbreak] is caused by ***[name of emerging virus]***. ***[Product name]*** kills similar viruses and therefore can be used against ***[name of emerging virus]*** when used in accordance with the directions for use against ***[name of supporting virus(es)]*** on ***[hard, porous/non-porous surfaces]***. Refer to the ***[CDC or OIE]*** website at ***[website address]*** for additional information.”

3. Make the following changes to the proposed label:

- a. Throughout the label, revise directions for use for “heavily soiled” to “visibly soiled”.
- b. On page 5, remove the heading “Food-contact surface bacteria”. The directions for use for food contact surfaces refer to a 1-minute contact time and not the 10 minute contact time listed for *Listeria*.
- c. On page 9,
 - i. Remove references to EPA and CDC.
 - ii. Revise the claims “This product meets AOAC efficacy testing requirements – or – standards for hospital disinfection” and “Meets AOAC germicidal spray standards for Hospital Grade Disinfectants”. AOAC does not set efficacy testing standards. The claims may be revised to indicate the product was testing using those AOAC methods.
 - iii. Claims for “germicidal” should be qualified according to the following:
<https://www.epa.gov/pesticide-labels/use-term-germs-antimicrobial-labels>
 - iv. Remove “grade” from the following claims: “Hospital [grade] [level] Disinfectant” and “Veterinarian [grade] [level] disinfectant” as this implies heightened efficacy. See Chapter 12 of the label review manual;
<https://www.epa.gov/sites/production/files/2018-04/documents/lrm-complete-mar-2018.pdf>
 - v. Removes “defends against” from the claim “Disinfects [defends against] [common] household surfaces” as it implies protection from disease.
 - vi. Remove “antiviral” from the following claim as it implies a drug use, “Effective against non-enveloped viruses* [[such as – or – e.g.,] [(] [norovirus], [rotavirus], [adenovirus], []) [which] [are broadly antiviral and capable of inactivating both enveloped and non-enveloped viruses*] “
 - vii. Remove eliminates from the claim “Eliminate(s) bacteria – and/or – viruses* that hide [lurk] [reside] where you [touch] [breathe] [work] [play] [live]” or revise to reflect the log reduction achieved (e.g. 99.9%).
- d. On page 10,
 - i. Revise claims to eliminate public health organisms (e.g. MRSA, *Pseudomonas*) as above in C, vii.
 - ii. Remove the claim “a new generation of protection” as it implies protection from disease.
 - iii. Remove “risk of” from the claim “Can help reduce the risk of cross contamination between treated hard, non-porous surfaces”
- e. On page 22,
 - i. Remove CPAP masks or specify external surfaces only.